

ABSTRACT

A thermal adhesion granulation process for preparing direct tableting formulations or aids is disclosed. The process comprises the step of subjecting all or part of a mixture comprising:

5 A) from about 5 to about 99% by weight of one or more diluent excipients and/or from 0 to about 99% by weight of a pharmaceutically active ingredient;

 B) from about 1 to about 95% by weight of a binder excipient;

 optionally with,

 C) from 0 to about 10% by weight of a disintegrant excipient;

10 to heating at a temperature in the range of from about 30 to about 130 °C under the condition of low moisture or low content of a pharmaceutically-acceptable organic solvent in a closed system under mixing by tumble rotation until the formation of granules.